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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/211,297	12/14/1998	WILLIAM J. BOYLE	A-451-F	7253

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AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320-1799

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/17/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/211,297

Applicant(s)

BOYLE, WILLIAM J.

Examiner

Regina M. DeBerry

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 May 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 20 May 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 37-57

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Claims 37-57 stand rejected under 35 USC 112, first paragraph scope of enablement. The rejections are maintained for reason of record. Applicant states undue experimentation would not be required to practice the claimed subject matter. Applicant states that the references cited do not discuss naturally occurring variants and provide no evidence that naturally occurring OPGbp variants could not be used as immunogens for the production of antibodies. Applicant states that the Sullivan Declaration demonstrates that the method could be applied to naturally occurring variants of OPGbp. Applicant's arguments are not found persuasive. As was stated in the last Office Action, it would take undue experimentation to carry out the invention. One skilled in the art would have to first isolate a naturally occurring variant of OPG. Applicant states that hybridization assays using an OPGbp probe could isolate naturally occurring variants. However to isolate variants genes with related function, one would have to use conditions of reduced stringency which would also pick up sequences that are not related to OPGbp (false positives). Once the gene is expressed, one would still need to demonstrate that this variant protein has the same activity as OPG binding protein (binding OPG). The references were cited to demonstrate the general nature of mutations and variants and how they affect protein structure, function or immunogenicity. A naturally occurring variant of OPG binding protein will not necessarily fold the same way and/or have the same action as wildtype OPGbp. An antibody made against a variant OPGbp is useless if the variant itself does not have the same activity as OPGbp. Thus the scientific reasoning and evidence as a whole indicate that the rejection should be maintained.

Claims 37-57 stand rejection under 35 USC 112, first paragraph written description. The rejections are maintained for reason of record. Applicant states that the invention relates to antibody composition which specifically bind to the recited OPGbp molecules and therefore the written description requirement must, in the first instance be applied to the antibody composition. Applicant states that Examiner's arguments and the cited case law have focused solely on OPGbp molecules to which the antibodies bind, and not on the invention which is the antibody composition. Applicant states that the Examiner has not provided evidence why the antibody compositions are not adequately described. Applicant's argument is not found persuasive. To make an antibody which binds specifically to an epitope of an OPGbp or naturally occurring variant thereof, one would have to actually have OPGbp and the naturally occurring variant of OPGbp. These proteins represent immunogens which are injected into animals to produce the antibodies. One cannot make a specific antibody against a protein if one does not have the protein. There is no evidence in the specification that Applicant had in its possession naturally occurring variants of OPGbp. The scientific reasoning and evidence as a whole indicate that the rejection should be maintained.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER